



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/776,667

02/10/2004

Gregory B. Altshuler

105090-0233

3788

21125

7590

08/14/2006

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER

JOHNSON III, HENRY M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,667	ALTSHULER ET AL.	
	Examiner	Art Unit	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 25-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>020206</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments filed June 15, 2006 have been fully considered but they are not persuasive.

The indicated allowability of claims 10-17 is withdrawn in view of the lack of disclosure in the specification. Rejections based on the newly cited reference(s) follow.

While the specification discloses applying radiation until a chromophore is activated, nothing is provided to teach or imply that a chromophore may activate due to accumulation of radiation. While paragraph 166 discloses a series of temporally spaced sessions yielding a cumulative effect on a patient, no mention is made of chromophores playing a role in the treatment.

The radiation of a chromophore with a low dose, in addition to being indefinite, is not disclosed as providing any unexpected result over known treatments. The disclosure by Rizoiu et al. that a wavelength is strongly absorbed is interpreted as a simple statement of PDT fact, that the wavelength is chosen to match the absorption of the selected photosensitizer, a fact well known to a skilled artisan. There is also a question as to how one would determine the chromophore has or has not been activated. Other teachings (U.S. Patent 6,149,895) include a dye that fades during the radiation process, providing feedback that activation has occurred. Rizoiu et al. teach dosages from 3 to 180 J/cm², this range being within that disclosed by the applicant in paragraph 166, thus qualifying as a lower dose.

Cipolla discloses the use of a broadband light source, such source inherently heating the areas with the radiation from the infrared range. The stain on the tooth that absorbs the radiation can be interpreted as part of the tooth structure or an exogenous chromophore. For example, a tea stain that has penetrated the tooth has become a part of the structure, where a tobacco stain has "been applied" to the surface by the act of using the tobacco product.

The whitening of teeth using radiation to activate a bleaching agent is well known, as is the application of the agent to the teeth using various means including an adhesive strip. To include a light-activated agent on the strip of Singh et al. would be obvious to one of skill in the art. Modification of the carrier matrix material (ethylene oxide) is not disclosed as producing any unexpected result and is therefore considered a design change of material of construction.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 1 implies a chromophore may store radiation in a cumulative manner until activated, yet no mention of this property is disclosed. The disclosed time between sessions is 1 to 30 days, making it unclear how the applied chromophore would remain in the oral cavity in a viable manner for a 24 hour period. Claim 10 cites applying a second chromophore, an action not described in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 43-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite as the bounds of the method cannot be determined. Numerous non-toxic chromophores are known with unique activation wavelengths yielding a method with essentially the broad generic steps of providing a chromophore and applying radiation. The term

Art Unit: 3739

low dose is indefinite as it is used in reference to a normal dose that has not been defined. With no disclosure of a chromophore being capable of accumulating radiation, activation cannot occur.

Claim 11 is indefinite as the base claim clearly indicates application of the second radiation after the application of the second chromophore clearly indicating a sequential application. The radiation cannot be both sequential and simultaneous.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-9 and 43-44 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,942,658 to Rizoïu et al. Rizoïu et al. teach a method for whitening teeth, the steps comprising, applying a whitening gel to the teeth to be treated, directing a laser light at the teeth using a laser power density of 3 W/cm^2 , activating the laser for 15 seconds, waiting for a period of about 1 minute and repeat the radiation steps a further three to ten times depending on the condition of the patient's teeth (Col. 8, lines 20-30). Rizoïu et al. further discloses the treatment times may be from 1-10 seconds (Col. 8, lines 4-7) yielding a dosage as low as 3 Joules per treatment. The power levels are within those cited by the applicant and, lacking any specific

Art Unit: 3739

means for determination of chromophore activation, are interpreted as a low dose. The whitening gel is disclosed as having a target chromophore (Col. 7, line 18) and an antibacterial agent (Col. 7, line 49). The wavelength of the radiation is taught as 700 to 11000 nanometers (Col. 6, lines 8-10).

Claims 19-23 and 25-34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,879,159 to Cipolla. Cipolla teaches a method for whitening teeth by radiating with a broadband light source. Xenon arc sources as taught are well known to have wavelengths exceeding 200 to 1000 nanometers. Cipolla discloses that in particular, light in the blue/green spectrum, is beneficial in tooth whitening procedures because light in this wavelength tends to be more readily absorbed by yellow/brown colored stain molecules but mostly reflected by the red colored tooth pulp in vital teeth (Col. 1, lines 45-48), thus teaching the stain molecules as chromophores. The infrared portion of the Xenon will inherently provide heating to the tooth.

Regarding claims 21-23, the type or location of a stain has no impact on the method steps.

Regarding claims 27 and 28, an endogenous agent is inherently in the target and has no impact on the method steps.

Regarding claims 32-34, the only active step is photoactivating, a mere irradiation of a target. The results are not cited as related to any specific fluence or wavelength to differentiate them from the basic photoactivation step. Where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

Art Unit: 3739

Claims 35-37 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication US 2003/0152528 to Singh et al. Singh et al. teach hydrogel compositions for tooth whitening using a hydrogel (paragraph 0114) that forms a polymeric matrix (paragraph 0047). The hydrogel composition may be light activated (paragraph 0020) and is capable of adhering to a tooth surface (paragraph 0022). The thickness is disclosed as from 80 to 800 microns (paragraph 0113) and the composition may include a plasticizer (paragraph 0025). Light activation implies the presence of a chromophore. Singh et al. teach the whitening agent is preferably a peroxide, implying the use of non-peroxides is known.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,942,658 to Rizoio et al. as applied to claim 1 above, and further in view of U.S. Patent

Art Unit: 3739

6,106,293 to Wiesel. Rizioiu et al. is discussed above, but does not disclose a film carrier.

Wiesel teaches a tooth whitening method using a carrier for the agents. The carrier may be stored in a sterile package in a rolled tape form or in differently sized strips (Col. 3, lines 43-46).

The strips or tape are interpreted as a film. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the carrier film as taught by Wiesel in the method of Rizioiu et al. as such carriers are common and well known in the art.

Claims 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,942,658 to Rizioiu et al. Rizioiu et al. teaches multiple applications of photosensitizers and radiation, but does not disclose the use of different photosensitizers for each session. Lacking any unexpected results or clear benefit to using another photosensitizer, this is considered routine experimentation that one of skill in the art may consider in treatment methods.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,942,658 to Rizioiu et al. as applied to claim 1 above, and further in view of U.S. Patent 6,106,293 to Wiesel. Rizioiu et al. is discussed above, but does not disclose application of radiation to heat the treated area. Wiesel teaches, in addition to applying the compound and irradiation, exposing the strip to virtually any light source in order to further accelerate heating of the peroxide, thereby accelerating the whitening of the teeth. The light source, for example, may be a heat lamp, a carbon dioxide laser, any short or long wave infrared laser, an argon laser, an ultraviolet laser, or a Yttrium Arsenic Gallium (YAG) laser (Col. 3, lines 13-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the heating as taught by Wiesel in the method of Rizioiu et al. as heating is common to enhance a reaction.

Art Unit: 3739

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0152528 to Singh et al. Singh et al. is discussed above, but does not disclose a matrix of ethylene oxide. Singh et al. teach many materials for the matrix including ethylene compositions. No specific properties or unexpected results are cited by the applicant for ethylene oxide and it is therefore considered an obvious design choice by one skilled in the art.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,942,658 to Rizoju et al. in view of U.S. Patent 6,525,819 to Delawter et al. Rizoju et al. are discussed above, but do not disclose measurement of tooth whiteness. Delawter et al. teach a colorimeter for dental applications that measures the color and reflectance of a tooth (Col. 1, lines 15-20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of measuring color as taught by Delawter et al. in the method of Rizoju et al. as an alternative to the manual comparison of colors as suggested by Delawter et al.

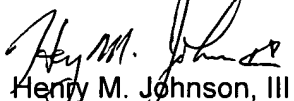
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Henry M. Johnson, III
Patent Examiner
Art Unit 3739